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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,095	01/07/2004	Bill E. Cham	P07389US01/BAS	2329
881 7590 08/03/2007 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER PESELEV, ELLI	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 08/03/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/752,095

Applicant(s)

CHAM, BILL E.

Examiner

Elli Peseev

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 16, 2007 has been entered.

Claims 24-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "solid preparation" (claims 24, 28, 29 and 43) not disclosed by the specification as originally filed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1623

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-42, 54-58, 60, 65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Cham et al (Cancer Letters, 55 (1990) 221-225).

Cham et al disclose the claimed composition useful for treating cancer.

Note that on page 12 of the specification, it is stated some degradation of glycoalkaloids under normal storage conditions can occur. Thus, the composition disclosed by Cham et al before storage is the same as the claimed composition.

Claims 24-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (Cancer Letters, 55 (1990) 221-225).

Cham et al disclose a composition comprising glycoalkaloids (BEC) useful for treating cancer (page 221). Cham et al further disclose that rhamnose inhibits the efficacy of BEC and that the aglycone solasodine is not effective against murine S180 (page 221). Thus, a person having ordinary skill in the art at the time of the present invention would have been motivated to remove rhamnose and aglycones from the BEC composition in order to improve efficacy of BEC., it would have been within the ordinary skill in the art at the time the present invention was made to use purified glycoalkaloids in a pharmaceutical composition for treating cancer.

Claims 40, 41, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (Cancer Letters, 55 (1990) 221-225) in view of Gatti et al (U.S. Patent No. 5,124,318).

Cham et al disclose a glycoalkaloid composition but do not disclose said composition in combination with a liquid carrier such as DMSO, acetic acid or lactic acid

Art Unit: 1623

or with a stabilizing agent. However, since Gatti et al conventional use of acetic acid and stabilizing agents in an injectable composition comprising glycosides (column 4) and He, a person having ordinary skill in the art at the time the claimed invention was made to add conventional additives disclosed by Gatti et al to a composition disclosed by Cham et al.

Claims 30, 31, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (Cancer Letters, 55 (1990) 221-225) in view of Daniels et al (U.S. Patent No. 4,053,591).

Cham et al disclose that aglycone solasodine is not effective against murine S189. Thus a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to remove aglycones from the composition disclosed by Cham et al using conventional chloroform purification process disclosed by Daniels et al (column 14, lines 50-52).

Applicant's arguments filed July 16, 2007 have been fully considered but they are not persuasive.

Applicant contends that Guerrero does not teach or suggest any process or method which would remove free sugars, which are degradation products of a glycoalkaloid, as claimed. Applicant further contends that Guerrero separates impurities from an alcoholic solution of solasodine glycosides by increasing or decreasing the volume of water to induce precipitation and that free sugars are highly water soluble and thus will remain in solution. This argument has not been found persuasive. The present claims are directed to a method of preparing a glycoalkaloid preparation which

Art Unit: 1623

includes the step of removing free sugars being degradation products such as by washing the extract with an aqueous solvent as set forth in claim 29. Further, In Example 1 on page 17 of the specification, free sugars are removed by washing with water. The addition of water disclosed by Guerrero is not seen to be different from the washing with water as encompassed by the present claims. Applicant has not provided any evidence that at least some free sugars have not been removed by the process disclosed by Guerrero.

Applicant contends that the specification provides evidence of enhanced efficacy of the present glycoalkaloid preparation. This argument has not been persuasive because said enhanced efficacy is to be expected in view of the teaching by Cham et al that rhamnose inhibits efficacy of BEC. Cham et al further disclose that rhamnose is not found in mammalian glycoconjugates but forms part of solasonine, solamargine and diglycosides of solasodine in BEC (page 221). It would have been within routine experimentation by a person having ordinary skill in the art at the time the claimed invention was made to determine the purity of the BEC composition disclosed by Cham et al and to further purify said composition in order to remove free sugars which are known to inhibit efficacy of said composition.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

  
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